

REMARKS

I. Amendment to the Specification

The specification has been updated with respect to the cross referencing of related applications. In addition, a minor and inadvertent spelling error has been corrected in the paragraph bridging pages 10 and 11 of the specification. A clean version of the paragraphs upon entry of the preliminary amendment is provided in Appendix B. Thus, no new matter has been added to the specification.

II. Amendments to the Claims

Claims 1-19, 22 and 23 have been canceled without prejudice. Claims 20 and 21 have been amended. Claims 24-59 have been added. Upon entry of the preliminary amendment, the claims will encompass, among other things, specific propellant-based compositions of a biologically active N-terminal fragment of parathyroid hormone. A clean version of the claims upon entry of the preliminary amendment is provided in Appendix B.

Support for the changes to the claims as well as the new claims is identified below. Additional support other than that identified below may exist in the specification for one or more changes and/or new claims.

Claim 20. Support for including a pharmaceutical bulking agent in the composition is provided in claim 5 as originally filed as well as on page 11, lines 8-11, and the sentence bridging pages 9 and 10 of the specification. Support for housing the composition "within a device designed for delivering an aerosolized bolus through the mouth" is provided in the abstract, on page 5, lines 7-9, and on page 12, lines 28-35. In combination, these passages support housing the claimed composition in a device (such as a nozzle or MDI) designed or intended primarily to deliver an aerosolized bolus through the mouth. The claimed composition is housed in the device prior to administration. In the case of an MDI, for example, the composition is usually housed in the canister portion of the device.

Claim 21. The changes made to claim 21 merely address matters related to form.

Claim 24. Aerosol propellants comprising a chlorofluorocarbon are supported by the sentence bridging pages 10 and 11 of the specification.

Claim 25. Specific chlorofluorocarbons are provided on page 11, lines 2-5, of the specification.

Claim 26. The specification discloses aerosol propellants comprising a hydrofluorocarbon in the sentence bridging pages 10 and 11.

Claim 27. Specific hydrofluorocarbons are recited on page 11, lines 5-7, of the specification.

Claim 28. Support for the subject matter of claim 28 is provided on page 5, lines 22-25, of the specification.

Claim 29. The bulking agents specifically provided in claim 29 are supported on page 10, lines 3-6, of the specification.

Claim 30. Support for PTH34 as an example of a biologically active N-terminal fragment of parathyroid hormone is found on page 8, lines 15-22, of the specification.

Claim 31. The specification discloses PTH38 as an example biologically active N-terminal fragment on page 8, lines 15-22.

Claim 32. General support for new independent claim 32 is found in claim 20 as originally filed. Support for compositions lacking a penetration enhancer is located on page 2, lines 25-27, of the specification. As in claim 20, support for housing the composition "within a device designed for delivering an aerosolized bolus through the mouth" is provided in the abstract, on page 5, lines 7-9, and on page 12, lines 28-35, of the specification.

Claim 33. Support for the subject matter of claim 33 is found in claim 21 as originally filed.

Claims 34, 35, 36, 37 and 38. See the comments with respect to claims 24, 25, 26, 27 and 28 for support of the subject matter of claims 34, 35, 36, 37 and 38, respectively.

Claim 39. Support for compositions comprising a bulking agent is found in the sentence bridging pages 9 and 10, and at page 11, lines 9-12, of the specification.

Claim 40. See the comments of claim 29 for support of the subject matter of claim 40.

Claim 41. Support for compositions further comprising an additive is found in specification in the paragraph bridging pages 9 and 10 (particularly at page 10, line 13) and at page 11, lines 8-19 (particularly at page 11, line 18).

Claim 42. Support for additives selected from the group consisting of surfactants, lower alcohols, chemical stabilizers and combinations thereof is found on page 11, lines 8-19, of the specification.

Claim 43. Specific support for surfactant additives is found on page 11, lines 11-13, of the specification.

Claim 44. The subject matter of claim 44 is found on page 11, lines 13-15, of the specification.

Claim 45. The subject matter of claim 45 is found on page 11, lines 8-13, of the specification.

Claim 46. Specific support in the specification for lower alcohol additives is found at page 11, lines 16-19.

Claim 47. Ethanol as an example of a lower alcohol is provided on page 11, lines 16-19, of the specification.

Claim 48. Specific support for chemical stability additives is found at page 11, lines 16-19, of the specification.

Claim 49. Support for the subject matter of claim 49 is found on page 10, lines 7-9, and on page 11, lines 8-11, of the specification.

Claim 50. Support for reciting a buffer as an example of a chemical stabilizer is provided on page 10, lines 7-9, and on page 11, lines 8-11, of the specification.

Claim 51. The subject matter of claim 51 is found on page 10, lines 9-11, of the specification.

Claim 52. A salt as an example of a chemical stabilizer is provided on page 10, lines 7-9, and on page 11, lines 8-11, of the specification.

Claim 53. The specific examples of salts recited in claim 53 are supported on page 10, lines 11-13, of the specification.

Claims 54 and 55. See the comments with respect to claims 30 and 31 for support of the subject matter of claims 54 and 55, respectively.

Claim 56. A method for treating a mammalian host suffering from or at risk of osteoporosis is provided on page 4, lines 12-17, of the specification. Support for "administering by inhalation through the mouth" and "an aerosolized bolus" is found on page 5, lines 7-9, of the specification. A therapeutically effective amount of a biologically active N-terminal fragment of

parathyroid hormone is located on page 12, lines 28-35, in the specification. See the comments provided above with respect to claim 20 for support of the pharmaceutical composition recited in claim 56.

Claim 57. Support for humans as an example of a mammalian host is provided on page 4, lines 12-17, of the specification.

Claim 58. With the exception of the recited composition, see the comments provided above with respect to claim 56 for support of the subject matter of claim 58. Support for the pharmaceutical composition discussed in claim 58 is provided above with respect to claim 32.

Claim 59. Support for humans as an example of a mammalian host is provided on page 4, lines 12-17, of the specification.

As support for the claimed subject matter is found in the application as filed, no new matter is introduced by the entry of the above-identified changes to the claims.

III. Conclusion

In view of the foregoing, Applicant submits that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Consequently, a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
Inhale Therapeutic Systems, Inc.

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By: Mark A. Wilson
Mark A. Wilson
Registration No. 43,275

Inhale Therapeutic Systems, Inc.
150 Industrial Road
San Carlos, CA 94070
(650) 631-3100 (Telephone)
(650) 631-3125 (Facsimile)